

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB 09-278-US)

In re Application of:)	
Akio Wakabayashi)	
Serial No. 10/517,908)	Examiner: Michael J. Anderson
Filed: January 30, 2006)	
For: System and method for efficient)	Art Unit: 3767
drainage of body cavity)	

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REASONS FOR REVIEW OF FINAL REJECTION

Applicant requests review of the final rejection mailed May 3, 2010, because the Examiner has clearly not set forth a proper and sufficient basis for rejecting any of the claims.

1. The Claimed Invention

Pending are claims 32-46, of which claims 32, 33, 34, 36, 41, 43 are independent. Each independent claim, in one way or another, recites a system for efficient drainage of a body cavity, and particularly for many claims, the chest area in the region of the heart.

2. Clear Error by the Examiner

The Examiner (i) rejected claims 32-43 and 46 as being allegedly anticipated by U.S. Patent No. 5,002,054 (Ash) and (ii) rejected claims 44 and 45 as being allegedly obvious over Ash. Thus, the Examiner rejected each of the independent claims as being allegedly anticipated by Ash. However, the Examiner clearly erred in rejecting the claims, because Ash does not teach (expressly or inherently) all of the elements of any of these claims. Therefore, Ash *cannot* anticipate any of the claims.

Ash discloses an interstitial filtration and collection device. However, this disclosed system of Ash is not a system for efficient drainage of a body cavity. Rather, the system of Ash is designed as an implantable filtration and collection device that is useful for monitoring glucose

and other physiological constituents. (See, e.g., Ash, column 10.) A close analysis of Ash in comparison to the independent claims reveals that the system of Ash has clear structural differences from Applicant's claimed invention and, therefore, the system of Ash would not act as an efficient drainage device in accordance with the claims.

For example, claim 36 recites, *inter alia*, a drainage device for draining a body cavity that comprises a tube with a plurality of holes formed into the tube sidewall, the "holes being of a size and quantity such that a suction force from any of said holes is insufficient to cause any significant injury to body tissue proximate a hole, while efficiently draining fluid from the body cavity." This is extremely important to Applicant's invention, for example, because "a transit time through the tube is a critical factor because blood must be removed out of the drainage tube before it clots" and "[d]ue to its high efficiency operating at high vacuum pressures, the present invention may advantageously reduce the incidence of subcutaneous emphysema (collection of air under the skin), unresolved pneumothorax, pleural effusion or cardiac tamponade." (Applicant's specification, page 5 and page 10.)

In contrast, Ash is an interstitial filtration and collection device. While the interstitial filtration and collection device includes a plurality of pores formed into a tube sidewall, the pores are not of a size and quantity such that a suction force from any of the pores efficiently drains fluid from the body cavity. As disclosed in Ash, the implantable filtration and collection device is for collecting a filtrate containing a physiological constituent of the body present in interstitial body space. (See, e.g., Ash, column 4, lines 34-36.) The pores of the filtration and collection device are "sized not to exceed a predetermined dimension corresponding to the size of the physiological constituent being filtered." (*Id.* at column 4, lines 46-49.) Ash explains that the fiber size may be selected based on the particular physiological constituent being filtered. For example, a fiber may be used having a pore size of 30,000 daltons. (See Ash, column 7, lines 23-33.) Ash explains that, alternatively, fibers can be used having increased pore sizes to filter larger physiological constituents. In particular, "increasing the pore sizes to a maximum

diameter of up to 100 microns would allow monitoring of cells, such as lymphocytes, phagocytes, granulocytes, fibroblasts, hormones, proteins such as collagen, and other cells residing in the interstitial space.” (*Id.* at column 7, lines 42-47.) Thus, it is clear that the pore sizes in Ash are selected for the purpose of filtering. Because the size of the pores in Ash are selected based on the particular physiological constituent being filtered, the pore size would not allow Ash to efficiently drain body fluid from a body cavity, as required by claim 36. Indeed, if one were to attempt to drain a chest cavity of a patient using the filtration device of Ash, the patient would likely be dead as a result. The amount of liquid the filtration device is capable of draining is totally different than the amount of liquid Applicant’s claimed invention is capable of draining, and the filtration device would not be nearly efficient enough to safely efficiently drain body fluid from a body cavity, as required by claim 36.

Accordingly, because Ash does not explicitly or inherently teach every element of claim 36, and indeed the most important elements, the Examiner has not made out the requisite case of anticipation. Therefore, Applicant submits that the Examiner clearly erred in rejecting claim 36 and that claim 36 is allowable.

Dependent claims 38 and 39 recite particular effective diameters of holes of Applicant’s drainage device. In particular, claim 38 recites an effective diameter of about 1mm and claim 39 recites an effective diameter of about 0.5mm. Applicants recognize that the Examiner interprets “on the order of 100 microns” to be 0.1mm to 0.9mm. Specifically, the Examiner states “[i]t is noted that pore sizes with magnitudes on the order of 100 microns or 0.1mm to 0.9mm overlap the required limitation range of about 0.5mm and about 1mm.” (Final office action, page 8.) However, Applicants submit that one of ordinary skill in the art would not interpret “on the order of 100 microns” to encompass a range as large as 0.1mm to 0.9mm (or 100 microns to 900 microns). Rather, “on the order of 100 microns” would be interpreted as about 100 microns or approximately 100 microns. Given that the device of Ash is intended for filtering a physiological

constituent of the body, it is clear from Ash that “on the order of 100 microns” means about 100 microns, not up to *nine times* greater than 100 microns.

With respect to claim 34, this claim recites, *inter alia*, a highly efficient drainage device for draining fluid from a body cavity that comprises a “tube having a plurality of holes having an area greater than that of a circle with an area around one half of an internal diameter of the tube.” Holes of such a size beneficially allow for highly efficient drainage of fluid from a body cavity and as noted above, yield the very important aspect of the invention of ensuring a suction force communicated within the body cavity to remove fluid but is insufficient to damage the tissues exposed in the vicinity of the drainage tubing. A close analysis of Ash reveals that Ash does not explicitly or inherently teach this claim feature mentioned above. Here again, Ash deals with tubing designed for *filtration*. Ash discloses that “[t]ubing having an inner diameter less than about 0.115” should be practicable for this purpose, while an inner diameter of 0.045” – 0.0055” is more preferred.” (Ash, column 8, lines 64-66.) As mentioned above, the pores are sized to about 100 microns. Such pores intended for filtering, however, would not have an area greater than that of a circle with an area around one half of an internal diameter of the tube. For example, a 100 micron pore does not have an area greater than a circle with an area around one half of an internal diameter of a 0.045” tube (i.e., a circle with a diameter of 1143 microns). Ash would not suggest holes of such a size because Ash is configured for filtration.

Accordingly, because Ash does not explicitly or inherently teach every element of claim 34, the Examiner has not made out the requisite case of anticipation. Therefore, Applicant submits that the Examiner clearly erred in rejecting claim 34 and that claim 34 is allowable.

With respect to claim 41, the claim recites a system for efficient draining of a body cavity that comprises a small caliber drainage tubing “having a plurality of holes . . . wherein said hole size and number are selected to yield a force of about 0.4N at a hole.” Once again, a close analysis of Ash reveals that Ash does not teach the claimed invention. Ash discloses high negative pressures between 300 and 750 mmHg. (See, e.g., Ash, column 8, line 57.) As

explained in Applicant's specification, suction force is a product of total suction area times vacuum pressure. Due to the size of the pores in Ash designed for filtration, the suction force at a hole in Ash would not be about 0.4N at a hole. The difference between the claimed invention and the system of Ash may once again be attributable to the clear structural differences and difference in purposes between the claimed invention and the filtration system disclosed in Ash. In light of the above, it is clear that the structure of Ash is different than the structure of the claimed invention of claim 41. Accordingly, because Ash does not explicitly or inherently teach every element of claim 41, the Examiner has not made out the requisite case of anticipation. Therefore, Applicant submits that the Examiner clearly erred in rejecting claim 41 and that claim 41 is allowable.

The other independent claims are also each allowable for the foregoing reasons and reasoning. For example, (i) claim 32 recites a system for efficient drainage of the chest area in the region of the heart, (ii) claim 33 recites a system for reducing cardiac tamponade by providing highly efficient drainage of the chest area in the region of the heart, and (iii) claim 43 recites a system for efficient drainage of a body cavity. Due to the different structure and purpose of Ash, Ash does not anticipate these claims.

For the foregoing reasons, the Examiner clearly erred in rejecting claims 32, 33, 34, 36, 41, and 43, and Applicant submits that the independent claims are allowable. Furthermore, without conceding any of the Examiner's assertions, Applicant submits that the dependent claims are allowable as well for at least the reason that they depend from the allowable independent claims. Accordingly, Applicant respectfully requests the panel to withdraw the rejections of all of the pending claims, and to direct that a Notice of Allowance be mailed.

Respectfully submitted,

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Dated: November 2, 2010